

Kentucky Department of Insurance

Pharmacy Benefit Manager Guide – Full Review

PBM ENTITY NAME _____ Incorporation/Formation Date _____

PBM Entity ID #: _____ Date of Receipt: _____ FEIN: _____

UR Registration # (if applicable): _____ Website Address _____

Address of Home Office: _____ City _____ State _____ Zip Code _____

Business Address: _____ City _____ State _____ Zip Code _____

Mailing Address: _____ P.O. Box _____ City _____ State _____ Zip Code _____

Phone Number _____ Fax Number _____ Business E-Mail Address _____

Contact Person _____ Contact's Phone Number _____ Contact's E-mail address _____

KRS 304.17A-162 (01) (a &b) PBM identify sources used to calculate reimbursement and establish process to appeal MAC pricing – appeal process		KRS 304.17A-162 (07) Policy to notify contractees with weekly updates to MAC and the actual cost		KRS 304.17A-162 (13) Reimbursement for drug products are available	
KRS 304.17A-162 (02) Appeal grants result in price update		KRS 304.17A-162 (08) Drug products and TEEs subject to MAC are available		45 CFR 156.22 Exceptions policy and policy to access retail pharmacy	
KRS 304.17A-162 (03) Identify sources used to establish MAC to determine reimbursement		KRS 304.17A-162 (09) Reimbursements are for specific drug products and TEEs		Other Policies: Sample response letter for MAC appeals, and Pharmacy and Therapeutics Committee	
KRS 304.17A-162 (04) Make lists available display each drug subject to MAC and actual MAC		KRS 304.17A-162 (10) Reimbursement for “B” drug products and TEEs		Paid \$1,000 to Kentucky State Treasurer Application fee	
KRS 304.17A-162 (05) & 304.2-165 Policy to provide requested info to department in order to resolve appeals		KRS 304.17A-162 (11) Reimbursement for “NR” or “NA” drug products and TEEs		Proof of financial responsibility in amount of \$1,000,000	
KRS 304.17A-162 (06) Policy to update and utilize updated MAC pricing every 7 days and notify all contractees		KRS 304.17A-162 (12) Reimbursement for drug product without TEE		Proof of registration with the Kentucky Secretary of State office in order to business in Kentucky	

Reviewer signature

Administration and Operation	Compliant	Need Additional Information RE:	Policy Reference
KRS 304.17A-162 (1) (a) PBM IDENTIFY SOURCES AND ESTABLISH APPEALS PROCESS RE: MAC PRICING			
Have a policy that PBM shall identify sources used to calculate drug reimbursement and establish a process to appeal and resolve disputes regarding maximum allowable cost pricing.	YES or NO		
KRS 304.17A-162 (1) (b) APPEAL PROCESS			
<p>Have a policy with detailed description of the MAC Pricing Dispute Appeal Process to be used by contracted pharmacies, pharmacy services and administration organizations of group purchasing organization, including the appeals policy and procedure, pursuant to KRS.17A-162 (1) (b).</p> <p>Appeals process should include following provisions:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Right to appeal limited to 60 days following initial claim; <input type="checkbox"/> The appeal shall be investigated and resolved by PBM within 10 calendar days; <input type="checkbox"/> The PBM shall respond to all appeals in a manner approved by the department <input type="checkbox"/> If an appeal is denied the PBM shall provide the following: <ul style="list-style-type: none"> <input type="checkbox"/> A.) the reason for the denial and <input type="checkbox"/> B.) identify the national drug code of a drug product (NDC) and <input type="checkbox"/> C.) identify the source where (NDC) may be purchased from a licensed wholesaler by contracted pharmacies at a price at or below the maximum allowable cost; and <input type="checkbox"/> If an appeal is granted then all provisions in KRS 304.17A-162 (2) (a-f) shall apply (See next section below): 	YES or NO		
KRS 304.17A-162 (2) (a-f) APPEAL GRANTS RESULT IN PRICE UPDATE			
<p>Have a policy:</p> <ul style="list-style-type: none"> <input type="checkbox"/> If a price update is warranted as a result of an appeal granted the PBM shall: <ul style="list-style-type: none"> <input type="checkbox"/> A.) make the change in the maximum allowable cost to the initial date of service the appealed drug was dispensed; <input type="checkbox"/> B.) adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the network of that PBM that filled a prescription for patients covered under the same health benefit plan to the initial date of service the appealed drug was dispensed; <input type="checkbox"/> C.) individually notify all other contracted pharmacies in the network of that PBM that a retroactive maximum allowable cost adjustment has been made as a result of a granted appeal effective to the initial date of service the appealed drug was dispensed; <input type="checkbox"/> D.) adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost if applicable to their contract; <input type="checkbox"/> E.) allow the appealing pharmacy and all other contracted pharmacies in the network that filled prescriptions for patients covered under the same health benefit plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed; and <input type="checkbox"/> F.) make retroactive price adjustments in the next payment cycle. 	YES or NO		

KRS 304.17A-162 (3) NATIONAL DRUG SOURCES USED TO ESTABLISH MAC FOR REIMBURSEMENT			
Have a policy to identify the national drug pricing compendia or sources used to obtain drug price data (in a manner established by administrative regulations promulgated by the department) for every drug for which the PBM establishes a maximum allowable cost to determine the drug product reimbursement.	YES or NO		
KRS 304.17A-162 (4) EACH DRUG SUBJECT TO MAC AND ACTUAL MAC			
Have a policy to identify the location of the PBM's comprehensive list of every drug subject to MAC for each drug and the actual maximum allowable cost for each drug	YES or NO		
Have a policy to make available the PBM's comprehensive list of every drug subject to MAC for each drug and the actual maximum allowable cost for each drug.	YES or NO		
KRS 304.17A-162 (5) & 304.2-165 REQUESTED INFO TO RESOLVE APPEAL PROVIDED TO DEPARTMENT			
Have a policy that upon request, information that is needed to resolve an appeal shall be made available to the department within 15 calendar days and if the department is unable to obtain information from the PBM appeal shall be granted to the appealing pharmacy.	YES or NO		
KRS 304.17A-162 (6) UPDATE MAC PRICING EVERY 7 DAYS AND NOTIFY CONTRACTEES			
Have a policy and procedure to be used for updating MAC pricing (for every drug PBM establishes MAC to determine reimbursement) every 7 days and the PBM's ability to provide notification to all contractees.	YES or NO		
KRS 304.17A-162 (7) NOTIFY CONTRACTEES WITH WEEKLY UPDATES TO MAC AND ACTUAL COST			
Have a policy and procedure indicating PBMs ability to provide notification to all contracted pharmacies to the pharmacists the weekly updates to the list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.	YES or NO		
KRS 304.17A-162 (8) DRUG PRODUCTS AND TEEs SUBJECT TO MAC ARE AVAILABLE			
<p>Have a policy to ensure every drug subject to PBM's maximum allowable costs are:</p> <ul style="list-style-type: none"> <input type="checkbox"/> A.) Generally available for purchase by pharmacists and pharmacies in Kentucky from a national or regional wholesaler licensed in Kentucky by the Kentucky Board of Pharmacy; <input type="checkbox"/> B.) Not obsolete, temporarily unavailable, or listed on a drug shortage list; and <input type="checkbox"/> C1.) Drugs that have an "A" or "B" rating in the most recent version of the United States Food and Drug Administration Approved (USDA) Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book; or <input type="checkbox"/> C2.) Drugs that have a "NR" or "NA" rating or have a similar rating by a nationally recognized reference. 	YES or NO		
KRS 304.17A-162 (9) REIMBURSEMENTS ARE FOR SPECIFIC DRUG PRODUCTS AND TEEs			
Have a policy to ensure that reimbursement for a drug subject to maximum allowable cost is based solely on specific drug and drugs that are therapeutically equivalent if the therapeutically equivalent drugs are listed in the most recent version of the Orange Book (which is USDA Approved Drug Products with Therapeutic Equivalence Evaluations).	YES or NO		
KRS 304.17A-162 (10) REIMBURSEMENT FOR "B" DRUG PRODUCTS AND TEEs			
Have a policy to ensure that reimbursement for a "B" rated drug subject to maximum allowable cost is based solely on specific drug and drugs that are not therapeutically equivalent to a "B" rating in the most recent version of the Orange Book.	YES or NO		

KRS 304.17A-162 (11) REIMBURSEMENT FOR “NR” OR “NA” DRUG PRODUCTS AND TEEs			
Have a policy to ensure that reimbursement for a “NR” or “NA” rating or similar rating by a nationally recognized reference subject to maximum allowable cost is based solely on that specific drug and other drugs with a “NR” or “NA” rating or similar rating by a nationally recognized reference that meets criteria for therapeutic equivalence used in the Orange Book	YES or NO		
KRS 304.17A-162 (12) REIMBURSEMENT FOR DRUG PRODUCT WITHOUT TEE			
Have a policy to ensure that reimbursement for a drug subject to maximum allowable cost is based solely on that drug if there is no other therapeutically equivalent drug.	YES or NO		
KRS 304.17A-162 (13) REIMBURSEMENT FOR DRUG PRODUCTS ARE AVAILABLE			
Have a policy to ensure that reimbursement for a drug subject to maximum allowable cost is not based on a drug that is obsolete, temporarily unavailable, listed on a drug shortage list, or that cannot be lawfully substituted.	YES or NO		
45 CFR 156.122 EXCEPTIONS POLICY AND POLICY TO ACCESS RETAIL PHARMACY			
Have an <i>Exceptions Policy</i> which allows an enrollee, designee, or prescribing provider to gain access to clinically appropriate drugs not otherwise covered by the plan, and includes a standard procedure.	YES or NO		
Have an <i>Exceptions Policy</i> which allows an enrollee, designee, or prescribing provider to gain access to clinically appropriate drugs not otherwise covered by the plan, and includes an expedited procedure.	YES or NO		
Have a policy that explains the process that gives the ability to access prescriptions from an in-network retail, unless special handling or another reason proves that the prescription cannot be provided by a retail pharmacy.	YES or NO		
OTHER POLICIES POLICY RE: PHARMACY AND THERAPEUTICS COMMITTEE, & SAMPLE LETTER			
Have a policy and procedure relating to the resolution of MAC pricing complaints which are filed with the Kentucky Department of Insurance, including timeframes and sample appeal response letter.	YES or NO		
Have a policy explaining any Pharmacy and Therapeutics committee membership standards and duties, including how often the committee meets, structure, and the decision-making process.	YES or NO		
OTHER REQUIREMENTS MAY BE VERIFIED BY LICENSURE			
Have proof of financial responsibility in the amount of one million dollars (\$1,000,000).	YES or NO		
Have proof of registration with the Kentucky Secretary of State’s office in order to do business in Kentucky.	YES or NO		
Have \$1,000 non-refundable fee made payable to the Kentucky State Treasurer, KRS 304.9-200(4).	YES or NO		